

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
For Syva Emit® II Plus Benzodiazepine Assay**

**1. Manufacturer and Contact Information:**

Manufacturer: Syva Company – Dade Behring Inc.  
20400 Mariani Ave.  
Cupertino, CA 95014

Contact Information: Paul Rogers  
Syva Company  
3403 Yerba Buena Road  
San Jose, CA 95161-9013  
Tel: 408-239-2000

**2. Device Classification Name:**

The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Benzodiazepine Test System" as Class II.

**3. Intended Use:**

The Syva Emit® II Plus Benzodiazepine Assay is a homogeneous enzyme immunoassay with a 200ng/mL or 300ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analysis of benzodiazepines in human urine.

**4. Device Description and Characteristics:**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMMA 1990.

The Syva Emit® II Plus Benzodiazepine Assay is a homogenous enzyme assay intended for use in the qualitative and semiquantitative analysis of benzodiazepines in human urine.

The Syva Emit® II Plus Benzodiazepine Assay has been found to be equivalent to the predicate device, Syva Emit® II Benzodiazepine Assay with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The Syva Emit® II Plus Benzodiazepine Assay showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a 97% agreement for the 200ng/mL cutoff and a 84% agreement for the 300ng/mL cutoff. The discordance between the test and predicate method can be explained by the fact that there are different calibrator drugs in the two methods. The calibrators used with the Syva Emit® II Plus Benzodiazepine Assay contain the benzodiazepine, lorazepam, while the calibrators used with the Syva Emit® II Benzodiazepine Assay contain the benzodiazepine, oxazepam. The use of lorazepam as the calibrator analyte increases the apparent sensitivity of the Syva Emit® II Plus Benzodiazepine Assay to various benzodiazepines.

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
For Syva Emit® II Plus Benzodiazepine Assay (cont.)**

**Spiked Sample Recovery:** In qualitative spike analysis of lormetazepam in negative human urine specimens, the Syva Emit® II Plus Benzodiazepine Assay using a cutoff of 200 ng/mL and a cutoff of 300 ng/mL correctly identified the spiked specimens containing less than or equal to minus 25% of the respective cutoffs as negative and the spiked specimens containing greater than or equal to plus 25% of the respective cutoffs as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Syva Emit® II Plus Benzodiazepine Assay. Negative human urine specimens were spiked with concentrations of lormetazepam at levels throughout the semiquantitative range of 40 to 900 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Syva Emit® II Plus Benzodiazepine Assay. Within this range, recovery was within 85-118% of nominal concentrations of spiked analyte.

**Precision:** A precision study was performed using Syva Emit® II Plus Benzodiazepine Assay in both the qualitative and semiquantitative modes. Acceptable within-run and total precision statistics for both the qualitative and semiquantitative assays were observed.

Qualitative results, determined from rates for controls and cutoff calibrator, demonstrated within-run precision with coefficients of variation (CV) ranging from 0.4 – 0.7% and total precision with CV ranging from 0.7 – 1.0%.

Semiquantitative results, determined from rates for controls and cutoff calibrator, demonstrated within-run precision with CV ranging from 1.8 – 5.2% and total precision with CV ranging from 2.3 – 5.6%.

**Sensitivity:** The sensitivity level of the Syva Emit® II Plus Benzodiazepine Assay is less than 15 ng/mL. This level represents the lowest concentration of benzodiazepines that can be distinguished from 0 ng/mL with a confidence level of 95%.

**5. Substantial Equivalence:**

In conclusion, Syva Company – Dade Behring Inc. considers the Syva Emit® II Plus Benzodiazepine Assay to be substantially equivalent to the Syva Emit® II Benzodiazepine Assay with regard to intended use, assay, sample, and overall performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JAN 27 2000**

Mr. Paul L. Rogers, Jr.  
Senior Manager, Regulatory Affairs  
Syva Company – Dade Behring Inc.  
3403 Yerba Buena Road  
P.O. Box 49013  
San Jose, California 95161-9013

Re: K993985  
Trade Name: Syva Emit® II Plus Benzodiazepine Assay  
Regulatory Class: II  
Product Code: JXM  
Dated: November 23, 1999  
Received: November 24, 1999

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

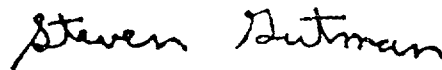
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K993985

**Device Name:** Syva Emit® II Plus Benzodiazepine Assay

**Indications for Use:**

The Syva Emit® II Plus Benzodiazepine Assay is a homogeneous enzyme immunoassay with a 200 ng/mL or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of benzodiazepines in human urine. Syva Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Syva Emit® II Plus Benzodiazepine Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Jean Cohen  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K993985

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)